In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-30V

(not to be published)

* *	Special Master Corcoran
LORINDA L. SCHNEIDER, *Guardian of:* M.A.M., *a minor*,	
Petitioner,	Filed: April 10, 2019
v.	
SECRETARY OF HEALTH AND HUMAN SERVICES,	Autism Spectrum Disorder; Measles-Mumps-Rubella Vaccine; No Expert; Dismissal Without Hearing.
Respondent.	
* *	

Lorinda Schneider, pro se, Salem, IN.

Justine Walters, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DISMISSING PETITION[1]

On January 5, 2018, Lorinda Schneider, on behalf of her minor grandchild, M.A.M., filed a Petition under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] The Petition alleges that the measles/mumps/rubella ("MMR") vaccine M.A.M. received on January 6, 2015, caused him to suffer an encephalopathy, resulting in a sensory disturbance disorder and developmental delay. Pet. at 1–3 (ECF No. 1). As noted in Petitioner's subsequent filings and throughout the medical record, M.A.M. was ultimately diagnosed with an autism

[1] Although I am not formally designating this Decision for publication, it will nevertheless be posted on the Court of Federal Claims's website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the Decision will be available to the public in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act.

spectrum disorder ("ASD").

A few months after the Petition's filing, I held a status conference with the parties. At that time, I explained to Petitioner that her case appeared indistinguishable from countless prior claims alleging a vaccine administered to a child caused an ASD—and that such claims had never found success. *See* Scheduling Order at 1, dated Apr. 20, 2018 (ECF No. 16). After more record documents were filed, I instructed Petitioner to show cause why the case should not be dismissed. Scheduling Order, dated June 26, 2018 (ECF No. 20). Petitioner subsequently filed her brief on November 20, 2018 (ECF No. 25) ("Mot."), and Respondent reacted to the filing with a brief (in conjunction with his Rule 4(c) Report) on March 1, 2019 (ECF No. 29). Having now had the opportunity to review these filings in light of the medical record, I find that dismissal of Petitioner's claim is appropriate.

Brief Summary of Relevant Medical Records

M.A.M. was born on December 24, 2013. Ex. 1 at 1, filed Jan. 5, 2018 (ECF No. 1-4); ECF No. 17[3] at 33, filed May 30, 2018. He was exposed to maternal drug use and smoking, as well as Hepatitis C, while in utero. ECF No. 17-5 at 78, filed May 30, 2018. His grandmother formally assumed custody of him on July 30, 2014. *Id.* at 19. Shortly thereafter, M.A.M. began regular visits with pediatrician Barbara Segoe, M.D. *See* ECF No. 17-7 at 1–12, filed May 30, 2018.

At his initial visits with Dr. Segoe on August 20, September 4, and September 29, 2014, M.A.M. presented with a number of issues, including candidiasis,[4] allergic rhinitis,[5] neonatal withdrawal symptoms due to his mother's drug use, and an upper respiratory infection. ECF No. 17-7 at 4, 7, 10–11. No concerns about his cognitive development were noted at these early visits, and at eight months old, his language skills had progressed to the point of "babbl[ing] with consonants." *Id.* at 8. At nine months, Dr. Segoe recorded that M.A.M. was able to say "dada" and "mama." ECF No. 17-7 at 90

Sometime in January 2015, M.A.M. received the haemophilus influenzae type B ("hib"), Hepatitis A, pneumococcal, and varicella vaccines.[6] ECF No. 17-6 at 55, filed May 30, 2018;

---

[3] Several of the documents filed by Petitioner were not given exhibit numbers. These documents will be referenced by their ECF numbers.

[4] Candidiasis is a fungal infection. *Dorland's Illustrated Medical Dictionary* 280 (32nd ed. 2012) (hereinafter "Dorland's").

[5] Allergic rhinitis refers to an allergic reaction resulting in inflammation of mucous in the nose. *Dorland's* at 1639.

[6] Records conflict as to the exact date of M.A.M.'s hib and pneumococcal vaccinations, but they appear to have been administered sometime in January 2015. *Compare* ECF No. 17-7 at 13 (hib and pneumococcal vaccines administered January 20, 2015) *and* ECF No. 17-6 at 55 (fourth doses of hib and pneumococcal vaccines administered on January 20, 2015) *with* Ex. 3 at 3 (hib and pneumococcal vaccines noted at January 6, 2015 visit).

ECF No. 17-7 at 13; Ex. 3 at 1–3, filed Jan. 5, 2018 (ECF No. 1-6). He unquestionably received the MMR vaccine on January 6, 2015. ECF No. 17-6 at 55; ECF No. 17-7 at 13. M.A.M. was noted to have macrencephaly[7] and macroglossia[8] at the January 6th visit. Ex. 3 at 3. The medical records do not indicate whether his language development was assessed at his twelve-month visit, but Petitioner asserts in her brief that M.A.M. was "speaking clearly" and had a vocabulary of nine words at that time. *See id.*; Mot. at 3. Petitioner also states in her brief that M.A.M. developed a fever after vaccination, and that his skin was sore and red around the injection site, though medical records do not confirm such an immediate post-vaccination reaction. Mot. at 3.

At a fifteen-month well-child visit on March 30, 2015, Petitioner reported that M.A.M. was demonstrating indicia of regression. His language abilities had deteriorated so that he was no longer saying "nana," "dada," or waving "bye-bye." ECF No. 17-6 at 76. Dr. Segoe assessed him with a speech delay and referred him for a hearing screening and early intervention services. *Id.* at 77. At a genetics screening in May 2015, M.A.M. was noted to have a vocabulary of four to five words and able to wave goodbye. ECF No. 17-4 at 62, filed May 30, 2018. However, at an appointment with Dr. Segoe in early June 2015, Petitioner reported her concern that M.A.M. had autism, as he was showing several concerning signs such as not responding to his name, flapping his hands, and banging his head on the floor. ECF No. 17-6 at 72. Ms. Schneider also suggested her view that vaccines cause autism, but Dr. Segoe did not embrace this possibility. *Id.*

Due to his demonstrated regression, M.A.M. underwent various tests in the following months. *See, e.g.*, ECF No. 17-6 at 69–70 (June 17, 2015 hearing evaluation); ECF No. 17-4 at 60 (July 30, 2015 genetics consultation). Throughout these evaluations, Petitioner repeatedly informed treaters that M.A.M. had developed a vocabulary of five to ten words before his twelve-month check-up, but had become essentially nonverbal shortly thereafter. *E.g.*, ECF No. 17-2 at 60, filed May 30, 2018; ECF No. 17-6 at 70. He was formally diagnosed with an ASD after a September 21, 2015 evaluation at Riley Hospital for Children in Indianapolis. ECF No. 17-5 at 17–18.

As detailed in Petitioner's brief and the medical record, M.A.M. has received a variety of treatments and therapies for his ASD since he was first diagnosed, largely thanks to Ms. Schneider's dedicated efforts to provide him with high-quality care. *See, e.g.*, ECF No. 17-4 at 40 (describing Ms. Schneider's attempts to modify M.A.M.'s diet; Epsom salt baths); ECF No. 17-5 at 37 (evaluation for shoe inserts to help with M.A.M.'s toe walking); Mot. at 5–6 (describing aids including safety bed, behavioral therapy, and more). At age four, he was noted to have good eye contact, but no expressive language ability. ECF No. 17-4 at 41.

---

[7] Macrencephaly refers to excessive brain growth. *Dorland's* at 1091.

[8] Macroglossia is an abnormally large tongue. *Dorland's* at 1093.

ANALYSIS

To receive compensation under the Vaccine Program, a petitioner must prove either (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to a vaccine identified on the Table that the petitioner or injured party received, or (2) that he suffered an injury that was actually caused by a vaccine. *See* §§ 11(c)(1), 13(a)(1)(A).

Petitioner has not formally asserted a claim arising from the Vaccine Table. However, an examination of the record does not uncover any evidence that M.A.M. likely suffered an encephalopathy as defined by the Table after receipt of the MMR vaccine. *See* 42 C.F.R. § 100.3(a)(III)(B) (2018). In general, to succeed on such a claim, a petitioner would need to establish *both* that the injured party experienced an "acute" encephalopathy—typically evidenced by a decreased change in consciousness (as that term is defined in the Qualifications and Aids to Interpretation ("QAIs"), 42 C.F.R. § 100.3(c)(2) (2018)) of sufficient severity to warrant hospitalization—and that the encephalopathy subsequently became "chronic" (that is, it lasted for at least six months). *Thompson v. Sec'y of Health & Human Servs.*, No. 15-1498V, 2017 WL 2926614, at *7–8 (Fed. Cl. Spec. Mstr. May 16, 2017).

The medical records filed in this case do not establish that M.A.M. experienced an acute encephalopathy within seventy-two hours of his MMR vaccination, as they do not establish that he experienced a significantly decreased level of consciousness. He was also never deemed by treaters to be sufficiently ill to warrant immediate hospitalization (despite Petitioner's assertions that his speech declined not long after vaccination). Indeed, the filed medical records reveal a several-month gap from the date of vaccination (January 6, 2015) to the March 2015 doctor's visit when M.A.M.'s developmental problems were first reported—too long a period without other evidence of medical concerns to support allegations of an acute encephalopathy.

Nor did M.A.M. subsequently experience a chronic encephalopathy. Although the evidence in the record from the six or more months after vaccination reveals ample concern for M.A.M.'s developmental state, it does not also suggest any concerns about neurologic status that might have prompted to treaters to conduct testing or obtain imaging. The evidence of M.A.M.'s developmental symptoms manifesting in the months after vaccination cannot persuasively be pointed to as proof of "encephalopathy"—they are at most *sequelae* of the alleged encephalopathy, and therefore it is circular reasoning to propose that they prove M.A.M. experienced an encephalopathy in the first place. *See R.V. v. Sec'y of Health & Human Servs.*, No. 08-504V, 2016 WL 3882519, at *34 n.80 (Fed. Cl. Spec. Mstr. Feb. 19, 2016), *aff'd*, 127 Fed. Cl. 136 (2016).

The same is true for Petitioner's argument that M.A.M. experienced a vaccine-caused encephalitis. Much like an encephalopathy claim, a petitioner must show that the injured party experienced acute encephalitis that resulted in a chronic encephalopathy. 42 C.F.R. § 100.3(c)(3)

(2018). Acute encephalitis is demonstrated by evidence of neurologic dysfunction—including focal cortical signs, cranial nerve abnormalities, visual field defects, abnormal presence of primitive reflexes, cerebellar dysfunction, or an acute encephalopathy—as well as evidence of an inflammatory process in the brain. 42 C.F.R. § 100.3(c)(3)(i) (2018). Although M.A.M.'s medical record does suggest that he experienced relatively rapid language skill regression shortly after his first birthday, it does not indicate that he experienced either the kind of neurologic dysfunction or inflammatory process that would qualify as acute encephalitis. And as noted above, the medical record does not support the contention that M.A.M. ultimately experienced a chronic encephalopathy.

A non-Table version of Petitioner's claim fares no better. Petitioner's brief makes some allegations that M.A.M. experienced a vaccine reaction (i.e. he was "very sore and red around the injection site and he would scream and cry if I accidentally touched him near the site of the injection" (Mot. at 3)), but there is no medical record corroboration that this reaction ever progressed to anything that was medically recognized or concerning. All that remains is the fact that (a) M.A.M. may have had an initial, if transient, reaction to the vaccine, and (b) Petitioner first noticed symptoms that were likely related to M.A.M.'s subsequently-diagnosed ASD thereafter (although they were only reported two to three months after vaccination). This is the classic temporal association between vaccination and injury that is recognized as insufficient to meet the preponderant standard for an entitlement award. *See McCarren v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 142, 147 (1997).

Give the above, I conclude that Petitioner will not be able to establish preponderant evidence in favor of her claim, and therefore the matter should not proceed, even if expert reports have not yet been obtained. In so deciding, I am reasonably taking into account the many prior cases alleging autism as a vaccine injury that have been decided in the Vaccine Program. Because of the timeframe between vaccination and discovery of M.A.M.'s first presenting ASD symptoms, in a case with a *different* causation theory and injury, the equities might support permitting the Petitioner to at least try to obtain an expert who could opine that the vaccines at issue likely caused the subsequent injury. But the question of the propensity of vaccines to cause *autism* has been largely foreclosed in the Vaccine Program by a host of extremely well-reasoned, carefully-considered cases decided over the past twelve years—and the MMR vaccine in particular was ruled out.[9] There is no justification in this case for expending the time and money

[9] Several years ago, more than 5,400 cases were initially filed under short form petition in the Omnibus Autism Proceeding ("OAP"), where thousands of petitioners' claims that certain vaccines caused autism were joined for purposes of efficient resolution. A "Petitioners' Steering Committee" was formed by many attorneys who represent Vaccine Program petitioners, with about 180 attorneys participating. This group chose "test" cases to represent the entire docket, with the understanding that the outcomes in these cases would be applied to cases with similar facts alleging similar theories.

The Petitioners' Steering Committee chose six test cases to present two different theories regarding autism causation. The first theory alleged that the measles portion of the MMR vaccine precipitated autism, or, in the alternative, that

for yet another expert on this topic given the extremely low odds that such an expert could offer an opinion based on new science more persuasive than all the expert opinions on the topic that have already been rejected over and over again. *See Hardy v. Sec'y of Health & Human Servs.*, No. 08-108V, 2015 WL 7732603, at *4–5 (Fed. Cl. Spec. Mstr. Nov. 3, 2015) (referencing eleven autism claims unsuccessfully tried, plus six that were rejected (over the petitioners' objections) without trial).

My decision is also rooted in the facts of this case when considered in light of previously-litigated matters involving causation theories highly similar to the present. *See generally* Mot.; Scheduling Order, dated July 6, 2018 (ECF No. 7). The existing medical record does not support the conclusion that the manifestation of M.A.M.'s autism was atypical for most children with ASDs. *See, e.g.*, *Snyder v. Sec'y of Health & Human Servs.*, No. 01-162V, 2009 WL 332044, at *39, *41–42, *44 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) (discussing manifestation of autism onset, noting loss of skills as typical; "most autism experts accept that skill loss does occur;" mean onset of symptomatology whether or not a child displays regression is between twelve and seventeen months of age). And, based on the available records, it appears that none of M.A.M.'s treating physicians opined that a vaccine was the cause of his ASD.[10]

MMR plus thimerosal-containing vaccines caused autism, while the second theory alleged that the mercury contained in thimerosal-containing vaccines could affect an infant's brain, leading to autism.

The first theory was rejected in three test case decisions, all of which were subsequently affirmed. *See generally Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review denied*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec'y of Health & Human Servs.*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review denied*, 88 Fed. Cl. 473 (2009), *aff'd*, 605 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec'y of Health & Human Servs.*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).

The second theory was similarly rejected. *Dwyer v. Sec'y of Health & Human Servs.*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec'y of Health & Human Servs.*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

Ultimately, a total of eleven lengthy decisions by special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit unanimously rejected petitioners' claims. These decisions found no persuasive evidence that the MMR vaccine or thimerosal-containing vaccines caused autism. The OAP proceedings concluded in 2010.

[10] The record from M.A.M.'s initial visit with Mary Lou Hulseman, M.D., on October 18, 2017, lists "adverse effect of vaccine, sequela" among his diagnoses. ECF No. 17-3 at 25–26, filed May 30, 2018. The written notes from that visit—which seemingly reflect Petitioner's report of M.A.M.'s history—state that Ms. Schneider first became concerned about M.A.M.'s development when he was eight months old, "when shortly after several vaccinations he became very low tone." *Id.* at 25. Dr. Hulseman noted further that "at 13 months of age within 48 hours of receiving the MMR [vaccine] he lost language and eye contact." *Id.* This record does not otherwise reflect Dr. Hulseman's opinion on the possibility of vaccine causation, however, and the record from M.A.M.'s subsequent visit with her in December 2017 does not list a vaccine reaction among his diagnoses or make any other mention of vaccines. *Id.* at 32–33.

Petitioner has also failed to establish that this case is distinguishable from the numerous autism injury claims already litigated in the Program. To support her claim, Petitioner references a single decision, *Mojabi v. Sec'y of Health & Human Servs.*, No. 06-227V, 2012 WL 6869685 (Fed. Cl. Spec. Mstr. Dec. 13, 2012), in which a claim that the MMR vaccine caused an ASD was purportedly found meritorious. Mot. at 8–9. But that decision is inapposite. *Mojabi* is a decision in which a petitioner did receive damages, but it was issued only after Respondent *conceded* the case based on his determination that the Petitioner had established facts to support a Table encephalitis that occurred five to fifteen days after vaccination. *Mojabi,* 2012 WL 6869685, at *1. Here, by contrast, Respondent has not conceded Petitioner's claim—and the mere fact that the Government conceded a *different* claim has no persuasive bearing on the outcome of this case. Moreover, *Mojabi* did not involve the reasoned determination by a special master that the claim was valid. And, as noted above, I do not find based on the present record that Petitioner *could* establish that M.A.M. experienced an encephalopathy or encephalitis after receipt of the MMR vaccine.

All in all, Petitioner cannot show in this case that the MMR vaccine was the cause of M.A.M.'s developmental problems. Petitioner might respond that her theory actually maintains that the vaccine precipitated an encephalopathy or encephalitis, and that *this* was the primary cause of her symptoms (making the vaccine incidental to the ASD). But the Court of Federal Claims has already noted in dealing with similar framing of an autism injury claim that petitioners cannot successfully recast a claim that a vaccine caused autism into an encephalopathy claim. *See, e.g., Cunningham v. Sec'y of Health & Human Servs.*, No. 13–483V, 2017 WL 1174448, at *5 (Fed. Cl. Jan. 25, 2017).

Because of the above, I conclude that Petitioner's claim as alleged lacks reasonable basis, and is appropriately dismissed. In so doing, I am aware of Petitioner's likely disappointment, and acknowledge her loving desire (motivated by a reasonable wish to provide good care for M.A.M.) to proceed with the claim. But I must balance such concerns against the unnecessary expenditure of judicial resources that will be occasioned by allowing this matter to go forward. My experience and reasoned judgment in adjudicating vaccine claims involving ASDs strongly informs my conclusion that this claim will not succeed where countless others failed. Because Petitioner has not—despite due opportunity—shown otherwise, I must DISMISS her claim.

Because Dr. Hulseman appears to document *Ms. Schneider's* views about the possibility of vaccine causation (rather than her own view as a physician), I find that the October 2017 record does not independently establish treater support for the idea that a vaccine caused M.A.M.'s ASD. Instead, it merely confirms that Petitioner has believed that vaccines played a causal role in bringing about M.A.M.'s condition for several years. Furthermore, as Ms. Schneider reported that M.A.M.'s regression began after an earlier set of vaccinations (rather than only after the January 2015 MMR), I find that this record in fact contravenes Petitioner's contention that M.A.M. suffered an adverse reaction to the MMR vaccine.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk SHALL ENTER JUDGMENT in accordance with this decision.[11]

Brian H. Corcoran
Special Master

[11] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.